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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,686	11/02/2001	Alan Kingsman	674523-2012	4344

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EXAMINER
HELMS, LARRY RONALD

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1642	13

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,686	Applicant(s) KINGSMAN ET AL.	
	Examin r Larry R. Helms	Art Unit 1642	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-95 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the restriction requirement it is noted that claims 1-5, 27-36, 40-41 have been withdrawn because the claims are directed to nonstatutory subject matter by the term "use". It is not clear if the claims are methods or products or multiple methods. In addition, claim 51 is not included because claim 51 claims a nucleic acid according to claims 46 or 47 which are method claims. It is also noted that it is unclear if SEQ ID NO:1-4, which appear to be amino acid sequences, correspond to SEQ ID NO:5-8, respectively, which appear to be DNA sequences. Applicant is requested to clarify this situation.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6-16, 53-66 in part, drawn to a DNA, vectors, method of expression of a scFv of SEQ ID NO:1, classified in class 536 subclass 23.53. **If any one of SEQ ID NO:5-8 is the DNA that encodes SEQ ID NO:1 then claims claiming the corresponding SEQ ID NO corresponding to SEQ ID NO:1 from claims 7-9 and 54-66 will be examined with this group.**

II. Claims 6-16, 53-66 in part, drawn to a DNA, vectors, method of expression of a scFv of SEQ ID NO:2, classified in class 536 subclass 23.53. **If any one of SEQ ID NO:5-8 is the DNA that encodes SEQ ID NO:2 then claims claiming the corresponding SEQ ID NO**

corresponding to SEQ ID NO:2 from claims 7-9 and 54-66 will be examined with this group.

III. Claims 6-16, 53-66 in part, drawn to a DNA, vectors, method of expression of a scFv of SEQ ID NO:3, classified in class 536 subclass 23.53. **If any one of SEQ ID NO:5-8 is the DNA that encodes SEQ ID NO:3 then claims claiming the corresponding SEQ ID NO corresponding to SEQ ID NO:3 from claims 7-9 and 54-66 will be examined with this group.**

IV. Claims 6-16, 53-66 in part, drawn to a DNA, vectors, method of expression of a scFv of SEQ ID NO:4, classified in class 536 subclass 23.53. **If any one of SEQ ID NO:5-8 is the DNA that encodes SEQ ID NO:4 then claims claiming the corresponding SEQ ID NO corresponding to SEQ ID NO:4 from claims 7-9 and 54-66 will be examined with this group.**

V. Claims 17, 23-25, 45, 69, 75-77, 79-83, 91, 95 in part, drawn to a scFv of SEQ ID NO:1, classified in class 530 subclass 388.85.

VI. Claims 17, 23-25, 45, 69, 75-77, 79-83, 91, 95 in part, drawn to a scFv of SEQ ID NO:2, classified in class 530 subclass 388.85.

VII. Claims 17, 23-25, 45, 69, 75-77, 79-83, 91, 95 in part, drawn to a scFv of SEQ ID NO:3, classified in class 530 subclass 388.85.

VIII. Claims 17, 23-25, 45, 69, 75-77, 79-83, 91, 95 in part, drawn to a scFv of SEQ ID NO:4, classified in class 530 subclass 388.85.

IX. Claims 18-22, 70-74 in part, drawn to an in vitro method of obtaining a scFv of SEQ ID NO:1, classified in class 435 subclass 7, for example.

X. Claims 18-22, 70-74 in part, drawn to an in vitro method of obtaining a scFv of SEQ ID NO:2, classified in class 435 subclass 7, for example.

XI. Claims 18-22, 70-74 in part, drawn to an in vitro method of obtaining a scFv of SEQ ID NO:3, classified in class 435 subclass 7, for example.

XII. Claims 18-22, 70-74 in part, drawn to an in vitro method of obtaining a scFv of SEQ ID NO:4, classified in class 435 subclass 7, for example.

XIII. Claims 26 and 78 in part, drawn to a method of affecting a disease in vivo with a scFv of SEQ ID NO:1, classified in class 424 subclass 130.1, for example.

XIV. Claims 26 and 78 in part, drawn to a method of affecting a disease in vivo with a scFv of SEQ ID NO:2, classified in class 424 subclass 130.1, for example.

XV. Claims 26 and 78 in part, drawn to a method of affecting a disease in vivo with a scFv of SEQ ID NO:3, classified in class 424 subclass 130.1, for example.

XVI. Claims 26 and 78 in part, drawn to a method of affecting a disease in vivo with a scFv of SEQ ID NO:4, classified in class 424 subclass 130.1, for example.

XVII. Claim 37 and 88 in part, drawn to a method of diagnosing a disease by determining the binding of a scFv of SEQ ID NO:1 to a sample, classified in class 435 subclass 7.2, for example.

XVIII. Claim 37 and 88 in part, drawn to a method of diagnosing a disease by determining the binding of a scFv of SEQ ID NO:2 to a sample, classified in class 435 subclass 7.2, for example.

XIX. Claim 37and 88 in part, drawn to a method of diagnosing a disease by determining the binding of a scFv of SEQ ID NO:3 to a sample, classified in class 435 subclass 7.2, for example.

XX. Claim 37and 88 in part, drawn to a method of diagnosing a disease by determining the binding of a scFv of SEQ ID NO:4 to a sample, classified in class 435 subclass 7.2, for example.

XXI. Claims 38-39 and 89-90 in part, drawn to a method of inducing an immune response by inoculating a mammal with a scFv of SEQ ID NO:1, classified in class 424 subclass 130.1, for example.

XXII. Claims 38-39 and 89-90 in part, drawn to a method of inducing an immune response by inoculating a mammal with a scFv of SEQ ID NO:2, classified in class 424 subclass 130.1, for example.

XXIII. Claims 38-39 and 89-90 in part, drawn to a method of inducing an immune response by inoculating a mammal with a scFv of SEQ ID NO:3, classified in class 424 subclass 130.1, for example.

XXIV. Claims 38-39 and 89-90 in part, drawn to a method of inducing an immune response by inoculating a mammal with a scFv of SEQ ID NO:4, classified in class 424 subclass 130.1, for example.

XXV. Claims 42 and 92, drawn to a canine 5T4 polypeptide of SEQ ID NO:14, classified in class 530 subclass 350.

XXVI. Claims 43-44, 93-94, drawn to a nucleotide sequence that encodes a canine 5T4 polypeptide, classified in class 536 subclass 23.1.

XXVII. Claims 46-50, 84 in part, drawn to a method of preventing or treating a disease with administration of a scFv of SEQ ID NO:1, classified in class 424 subclass 130.1, for example.

XXVIII. Claims 46-50, 84 in part, drawn to a method of preventing or treating a disease with administration of a scFv of SEQ ID NO:2, classified in class 424 subclass 130.1, for example.

XXIX. Claims 46-50, 84 in part, drawn to a method of preventing or treating a disease with administration of a scFv of SEQ ID NO:3, classified in class 424 subclass 130.1, for example.

XXX. Claims 46-50, 84 in part, drawn to a method of preventing or treating a disease with administration of a scFv of SEQ ID NO:4, classified in class 424 subclass 130.1, for example.

XXXI. Claims 67-68 in part, drawn to a method of preparing a scFv of SEQ ID NO:1, classified in class 435 subclass 69.6, for example.

XXXII. Claims 67-68 in part, drawn to a method of preparing a scFv of SEQ ID NO:2, classified in class 435 subclass 69.6, for example.

XXXIII. Claims 67-68 in part, drawn to a method of preparing a scFv of SEQ ID NO:3, classified in class 435 subclass 69.6, for example.

XXXIV. Claims 67-68 in part, drawn to a method of preparing a scFv of SEQ ID NO:4, classified in class 435 subclass 69.6, for example.

XXXV. Claims 85-86 in part, drawn to a method of in vivo imaging with a scFv of SEQ ID NO:1, classified in class 424 subclass 178.1, for example.

XXXVI. Claims 85-86 in part, drawn to a method of in vivo imaging with a scFv of SEQ ID NO:2, classified in class 424 subclass 178.1, for example.

XXXVII. Claims 85-86 in part, drawn to a method of in vivo imaging with a scFv of SEQ ID NO:3, classified in class 424 subclass 178.1, for example.

XXXVIII. Claims 85-86 in part, drawn to a method of in vivo imaging with a scFv of SEQ ID NO:4, classified in class 424 subclass 178.1, for example.

XXXIX. Claim 87 in part, drawn to a method of screening for agents with a scFv of SEQ ID NO:1, classified in class 435 subclass 7.1, for example.

XXXX. Claim 87 in part, drawn to a method of screening for agents with a scFv of SEQ ID NO:2, classified in class 435 subclass 7.1, for example.

XXXXI. Claim 87 in part, drawn to a method of screening for agents with a scFv of SEQ ID NO:3, classified in class 435 subclass 7.1, for example.

XXXXII. Claim 87 in part, drawn to a method of screening for agents with a scFv of SEQ ID NO:4, classified in class 435 subclass 7.1, for example.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV, VI-VIII, XXV, XXVI represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleic acids of Group I-IV and XXVI, the protein of Group IXXV, and the antibody of Groups VI-VIII are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA, and the antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening, the polypeptide can be used for methods of treatment, and the antibody can be used to immunopurify the antigen, for example. In addition within each group of I-IV and VI-VIII each of the products are distinct because each scFv has a distinct sequence and each DNA encoding each scFv would also be distinct. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-IV, VI-VIII, XXV, XXVI are patentably distinct.

The methods of Inventions IX-XXXXII differ in the method objectives, method steps and parameters and in the reagents used. Inventions IX-XII recites an in vitro method of obtaining a scFv; Inventions XIII-XVI recites a method of affecting a disease in vivo with a scFv; Inventions XVII-XX recites a method of diagnosing a disease by determining the binding of a scFv; Inventions XXI-XXIV recite a method of inducing an immune response by inoculating a mammal with a scFv; Inventions XXVII-XXX recite a

method of preventing or treating a disease with administration of a scFv; Inventions XXXI-XXXIV recite a method of preparing a scFv; Inventions XXXV-XXXVIII recite a method of in vivo imaging with a scFv and Inventions XXXIX-XXXXII recites a method of screening for agents with a scFv. In addition, within each of the Grouped inventions each are distinct because each method uses a distinct scFv with a distinct SEQ ID NO. In addition, the methods of Groups IX-XII and XXXI-XXXIV are distinct because the methods of IX-XXII require a phage library and Groups XXXI-XXXIV do not necessarily require this and can be produced by immunizing with an antigen. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions IX-XXXXII differ in the method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions VI-VIII and IX-XXXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the single chain antibody of groups VI-VIII can be used in a materially different method such as to purify the antigen in addition to any of the materially different methods of Groups IX-XXXXII.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter and different classifications, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,
Larry R. Helms Ph.D.
703-306-5879

LARRY R. HELMS, F
PRIMARY EXAMIN

LARRY R. HELMS, PH.D
PRIMARY EXAMINER